

Amendments to the Claims:

This listing of the claims replaces all prior versions, and listings, of claims in the present application:

Listing of the Claims:

Claim 1 (currently amended): An orally deliverable pharmaceutical once daily sustained release composition comprising a therapeutically effective amount of pramipexole or a pharmaceutically acceptable salt thereof, a starch, a hydrophilic polymer, and at least one pharmaceutically acceptable excipient, said composition exhibiting at least one of (a) an in vitro release profile wherein on average no more than about 20% of the pramipexole is dissolved within 2 hours after placement of the composition in a standard dissolution test conducted according to USP 24 using Apparatus 1 with a spindle rotation speed of 100 rpm and a dissolution medium of 0.05M phosphate buffer, pH 6.8, at 37°C; and (b) an in vivo pramipexole absorption profile following single dose oral administration to healthy adult humans wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours wherein said composition comprises a full daily dose contained in a single dosage unit, further wherein said composition, when administered once daily, exhibits a bioavailability substantially equivalent to an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation administered three times a day.

Claim 2 (cancelled).

Claim 3 (currently amended): The composition of claim 2 1 wherein no more than about 12% of the pramipexole dissolves within 1 hour in said test.

Claim 4 (currently amended): The composition of claim 2 1 wherein time to reach 50% dissolution is at least about 4 hours.

Claim 5 (currently amended): The composition of claim 2 1 wherein time to reach 50% dissolution is at least about 6 hours.

Claim 6 (currently amended): The composition of claim 2 1 wherein time to reach 50% dissolution is at least about 8 hours.

Claim 7 (currently amended): The composition of claim 2 1 wherein time to reach 50% dissolution is at least about 12 hours.

Claim 8 (original): The composition of claim 1 that exhibits an in vivo pramipexole absorption profile following single dose oral administration to healthy adult humans wherein the time to reach a mean of 20% absorption is greater than about 2 hours and/or the time to reach a mean of 40% absorption is greater than about 4 hours.

Claim 9 (original): The composition of claim 8 wherein the time to reach a mean of 40% absorption is at least about 5 hours.

Claim 10 (original): The composition of claim 8 wherein the time to reach a mean of 40% absorption is at least about 6 hours.

Claim 11 (cancelled).

Claim 12 (original): The composition of claim 1 that, following single dose administration of 0.375 mg, expressed as pramipexole dihydrochloride monohydrate equivalent, exhibits a maximum plasma concentration (C_{max}) of pramipexole that is not greater than about 0.3 ng/ml.

Claim 13 (original): The composition of claim 1 that exhibits a time to reach maximum plasma concentration (T_{max}) of pramipexole that is at least about 6 hours following administration of the composition.

Claim 14 (original): The composition of claim 1 that exhibits a time to reach maximum plasma concentration (T_{max}) of pramipexole that is at least about 8 hours following administration of the composition.

Claim 15 (original): The composition of claim 1 that exhibits a pharmacokinetic profile consistent with steady-state plasma concentrations having a fluctuation ratio that is not substantially greater than that of an equal daily dose of an immediate-release pramipexole dihydrochloride reference formulation, administered three times a day.

Claim 16 (original): The composition of claim 1 that comprises release-modifying means effective to provide said in vitro release profile and/or said in vivo pramipexole absorption profile.

Claim 17 (original): The composition of claim 16 wherein said release-modifying means is selected from the group consisting of a polymer matrix wherein the pramipexole is dispersed; a release-controlling layer or coating; and an osmotic pump.

Claim 18 (original): The composition of claim 1 wherein the pramipexole is in a form of a pharmaceutically acceptable salt thereof having moderate to high solubility in water.

Claim 19 (original): The composition of claim 18 wherein said salt is pramipexole dihydrochloride.

Claim 20 (original): The composition of claim 1 that is in the form of discrete dosage units.

Claim 21 (original): The composition of claim 20 wherein the amount of pramipexole in each dosage unit is sufficient to provide a daily dose in one to a small plurality of dosage units administered at one time.

Claim 22 (cancelled).

Claim 23 (original): The composition of claim 20 that comprises about 0.1 to about 10 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

Claim 24 (original): The composition of claim 20 that comprises about 0.2 to about 6 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

Claim 25 (original): The composition of claim 20 that comprises about 0.3 to about 5 mg pramipexole, expressed as pramipexole dihydrochloride monohydrate equivalent, per dosage unit.

Claim 26 (withdrawn - currently amended): A method of treatment of a subject having a condition or disorder for which a dopamine receptor agonist is indicated, the method comprising orally administering to the subject, not more than once daily, the composition of ~~any of the preceding claims~~ claim 1.

Claim 27 (withdrawn): The method of claim 26 wherein the condition or disorder is Parkinson's disease or a complication associated therewith.